

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****Application of**

Applicant(s) : John E. Davies et al.  
Application No. : 10/598,597  
Filed : October 11, 2007  
Title : Serum-Free Suspension Culture System for Mesenchymal Stem Cells  
Examiner : Janet L. Epps-Smith  
Attorney Docket : 1716-30/AMK  
Art Unit : 1633

**DECLARATION UNDER 37 C.F.R. § 1.132**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

The undersigned, Dolores Baksh, Ph.D., declares and states:

I am an inventor of the above-captioned patent application, U.S. Application No. 10/598,597, with a priority filing date of March 5, 2004, entitled "Serum-Free Suspension Culture System for Mesenchymal Stem Cells." I am currently Associate Director of Research in the Research and Development Department of the company, Organogenesis, Inc. The technology of the company encompasses living cell technology that includes progenitor cells. I am the subject of the attached Curriculum Vitae and author of the publications shown on the list attached to the Curriculum Vitae. On the basis of the information and facts contained in the documents, I submit that I am an expert in the fields of mesenchymal stem cells (MSC), mammalian cell culture processes, and tissue engineering. I have published, in the field of MSCs, scientific publications, review articles, and book chapters. In addition, my doctoral thesis involved developing cell culture processes for expanding MSCs. In my current position I am also intimately involved in the manufacturing process for progenitor cells and developing cultivation methods/cell culture technologies for mammalian cells, including protocols for expanding cells in high-density scalable

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processes. As Organogenesis is a company focusing on tissue engineering/regenerative medicine, I am involved in taking progenitor cells and building products with regenerative medicine capabilities. In and of itself, from my doctoral, post-doctoral, and current position, it is my opinion that I have the relevant expertise in this field to opine on the subject matter to which this Declaration is directed and also that I am qualified to speak about the skill and knowledge of the person of ordinary skill in these fields as of March 5, 2004.

Furthermore, I have read and understand the subject matter of the above-captioned application. I have read and understand the non-final Office Action dated June 12, 2009, the final Office Action dated January 20, 2010, and the cited references, WO 02/086104 (U.S. 2004/0137612) and U.S. 6,617,159 (Cancedda).

WO 02/086104

On page 2 of the final Office Action, the claims are rejected on the grounds that WO 02/086104 describes a process for culturing stem or progenitor cells in non-static, non-adherent suspension culture in serum-deprived nutrient medium. I do not agree for the reasons that I will set out below.

In the reply to the non-final Office Action (on page 5), we explained that WO 02/086104 directs the reader to grow the progenitor cells in non-static, non-adherent culture in serum-containing medium and to differentiate the progenitor cells in static culture in a serum-deprived medium. I reiterate that position. WO 02/086104 describes non-static culturing in serum to grow the progenitor cells and static culturing in defined medium to differentiate the expanded progenitors. But, in neither case, does WO 02/086104 teach combining serum-deprived medium and non-static culture for growing the progenitors.

Our reply was based on the Examiner's having cited paragraph [0048].

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In the Examiner's response to our discussion, however, the Examiner cites paragraph [0079] as follows.

Contrary to Applicant's assertions Baksh et al. teach the following at ¶ [0079].  
[F]or differentiation into chondroblasts, the progenitors can be grown in serum-free DMEM supplemented with TGF-beta in suspension culture, for about 14 days or more. This passage clearly teaches the use of non-static conditions in a serum-free culture of progenitor cells, and therefore reads on claims 1-3 and 8-11.

This text describes an assay for differentiating progenitors into chondrocytes. The Examiner interprets the term "suspension" to mean "non-static." That is incorrect. What Baksh meant by "suspension" was merely non-adherent.

A person of ordinary skill in the field would have read this text and would have understood that it was referring to static conditions. In the art of inducing chondrogenesis, it is standard to induce chondrogenesis under static conditions. Therefore, it would have been understood by the person of ordinary skill in the art that Baksh did not recommend, disclose, or suggest, in any way, conducting the chondrogenesis differentiation protocol under non-static conditions.

The reason for that is that inducing chondrogenesis requires a very specific developmental program. The cells that are subjected to the differentiation conditions must secrete certain types of extracellular matrix. The primary one is collagen type II. If one were to conduct the differentiation protocol under non-static conditions, such as stirred suspension, aggregates would form. This would, most likely, induce the production of collagen type I. Thus, one would not obtain chondrogenic tissue, which is the goal of the differentiation protocol taught by Baksh. To obtain chondrogenic tissue, this must be done under static high-density pellet culture. This means that one would seed the cells at very high density, typically in a 96 well plate, under static conditions. One would then add serum-free or chemically-defined medium to induce chondrogenesis. Accordingly, the Examiner's interpretation is inconsistent with what someone skilled in the art would actually have understood and acted upon to induce chondrogenesis.

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In addition, non-static culture conditions would create other impediments to the differentiation process. Non-static culture, for example, would induce shear stresses on the cells. Again, this would change the cell phenotype and the type of collagen production would favor collagen type I over collagen type II (which is characteristic of the chondrogenic collagen template).

Furthermore, the Examiner interprets the passage as describing growing progenitor cells in serum-free medium. This is not correct, either. The stem and/or progenitor cells do not actually grow; they only differentiate. With the addition of TGF- $\beta$ , the phenotype of the starting cells immediately begins to change from less differentiated to cells that are differentiated along the chondroblast lineage. Furthermore, TGF- $\beta$  immediately induces differentiation.

So, there are at least two differences: (1) the cited text ([0079]) does not describe non-static culture; and (2) the cited text describes differentiating the stem or progenitor cells, not growing them.

WO 02/086104 in view of U.S. 6,617,159

On page 6 of the final Office Action, the Examiner states

12. Baksh et al does not teach the use of a serum-free medium for the expansion of mesenchymal cells. However, the methods of Baksh et al. recite wherein a suitable medium for culturing non-hematopoietic cells types, including mesenchymal progenitor cells is used.

13. Cancedda et al. teach methods comprising the use of serum free media for the growth and proliferation of mesenchymal stem cells in culture. See the following embodiments of Cancedda et al set forth on page 3 of this reference:

On page 7 of the Office Action, the Examiner concludes that it would have been obvious to grow mesenchymal stem cells in non-static suspension culture as taught by WO 02/086104, but to use serum-free medium because 6,617,159 reports growing mesenchymal stem cells in serum-free medium. I do not agree with the Examiner's position on obviousness.

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I understand that obviousness has two requirements. First, there must have been motivation to grow MSCs in non-static culture with the medium of Cancedda (i.e., defined). Second, there must have been a reasonable expectation that MSCs would be successfully grown under these conditions. In my opinion, neither of these requirements was met.

The serum-free medium of Cancedda is effective with adherent cells. Example 1 clearly shows that cells are plated in anchorage-dependent conditions. Pre-coating with 2% gelatin is designed to favor adhesion of the cells in serum-free conditions.

The person of ordinary skill in the field would not have been motivated to apply medium designed for adherent cells to non-adherent cells. One would not have simply equated an adherent MSC with a non-adherent MSC to conclude that the medium of Cancedda would successfully support the growth of non-adherent MSCs. No scientist in the field would have thought this way. They would have known that growing cells on an adherent substrate results in cells that have specific receptors and require specific sets of growth factors.

The condition of adherence, in and of itself, selects cells that respond to a particular set of growth factors, adhesion receptors, and the like. Accordingly, the cell populations selected in suspension or under adherent conditions, are biologically different. Cells have already acquired a certain surface receptor repertoire because they have attached to a culture dish. For example, cells selected for adherent growth and put back into non-static culture, with or without serum, form aggregates and die.

As an example, any of the integrin receptors will be highly upregulated on adherent culture system. For example, CD49e is expressed on adherent cells almost 99%. One cannot then successfully culture these cells in suspension. But if there is a threshold lower expression level of CD49e, these cells can be grown in suspension. However, this threshold lower expression level (approximately 10% to 20%) is never obtained culturing an MSC under adherent culture conditions. The numbers approximate 100%.

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Therefore, these cells cannot simply be removed from the plate and grown in suspension culture, even in the same conditions that they would be grown according to Cancedda.

We do know from published work from our own laboratory (Appendix A attached) as well as the scientific literature, that cells derived from suspension culture (MSCs) are phenotypically different from the ones derived under adherent conditions. The surface markers expressed on these two cell types are very different. So, when these cells are isolated under these two very different culture paradigms, the resulting cells are going to express surface markers that are very different. It is even possible that the non-adherent cells represent more of a stem/progenitor population from which adherent cells can be produced. That is, that the adherent cells are more narrowly differentiated than the non-adherent stem/progenitor population. In fact, the non-adherent cells that we have made can be converted to an adherent cell type after the fact. They will then express the same or similar markers as are expressed on adherent cells that have not gone through a non-adherent phase. The reverse, however, is not true. That is, we have not been able to convert an adherent population back into suspension culture to have those cells grow under non-adherent serum-free conditions. That is because the different surface markers require different growth factors for proliferation.

The point of this discussion is that cells in suspension and cells that are adherent are two different cell populations. They do not express the same receptors. Accordingly, they likely require a different set of growth factors. Therefore, a researcher in the field would not have expected that growth conditions that apply to one could be successfully applied to the other. If they did expect this, in my opinion, it would not have been a reasonable expectation.

Therefore, the person in the field, in my opinion, would not have been motivated to try to use the Cancedda protocol on the same cells in suspension. They would have realized that the non-adherent cells could be very different in terms of adaptability to growth conditions.

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Accordingly, it is my opinion that the person of ordinary skill in this field would not have found it obvious to make the modification that the Examiner suggests for the reasons I have given above.

**Conclusion**

My opinion is that the person of ordinary skill in the field would not have been positively motivated to modify the process of WO 02/086104. On the contrary, in view of the expected requirements of adherent cells and non-adherent cells, the artisan would not have been motivated to try that approach and would not have had a reasonable expectation of success if they had tried that approach.

I declare that all statements made herein as my own knowledge are based on a good faith belief that they are true and any statements made on information and belief are made in good faith.

X 05/19/2010



Date

Dolores Baksh, Ph.D.

11529584.1

# **DOLORES BAKSH, Ph.D.**

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## **WORK ELIGIBILITY**

US permanent resident.

## **SUMMARY OF SKILLS**

- Over 10 years of research experience, with experience in biomaterials and stem cell uses in musculoskeletal and skin diseases
- Involved in the conception and inception of intellectual property and co-authored 4 PCT filing applications
- Published over 13 peer-reviewed journals and book chapters
- Worked on several cross-functional teams geared toward product launch
- Data analysis and report writing (SOPs), written and oral presentation of scientific data
- Computer software: PC and MAC Microsoft Office packages, statistical programs (e.g., Sigma Plot)

## **EDUCATION**

1999-2004	<b>Ph.D.</b> , Department of Chemical Engineering and The Institute of Biomaterials and Biomedical Engineering (IBBME), University of Toronto, Canada <b>Thesis title:</b> Adhesion-Independent Survival and Expansion of Bone Marrow-Derived Mesenchymal Progenitor Cells in Stirred Suspension Bioreactors <b>Advisors:</b> Drs. John E. Davies (D.D.S., Ph.D.) and Peter W. Zandstra (Ph.D.)
1997-1999	<b>M.A.Sc.</b> , Department of Chemical Engineering (Collaboration with IBBME), University of Toronto, Canada <b>Thesis title:</b> A comparison of 3-dimensional calcium phosphate scaffolds for candidate bone tissue engineering constructs <b>Advisor:</b> Dr. John E. Davies (D.D.S., Ph.D.)
1995-1997	<b>B.A.Sc.</b> , Department of Chemical Engineering, University of Toronto, Canada <b>Honors:</b> Dean's Honors List (all years), graduated with Honor Standing
1991-1995	<b>B.Sc.</b> , Faculty of Arts & Sciences, University of Toronto, Canada <b>Honors:</b> Graduated with Distinction, Golden Key Honor Society

## **WORK EXPERIENCE**

**Organogenesis Inc., Canton, MA, US** June 2007 – Present

Associate Director of Research, R&D – Current position

- Manager of the Applied Cell Biology Group in R&D
- Manage 7 Research FTEs

R&D Group Manager, Applied Stem Cell Biology Group

- Hired as a Senior Scientist I, with 1 direct report to perform research on strengthening current product(s).
- Via a R&D restructure, promoted to Group Manager of Emerging Technologies with 4 direct reports.
- In current position, lead team in the development of next generation product concepts in advanced wound care through managing and directing research, pre-clinical studies and cross-functional collaborations with regulatory, marketing and early commercial development teams within the organization.
- Manage sponsored research contract collaborations.
- Provide presentations to Executive team for technology acquisition, due diligence and publication planning.
- Filed 1 invention disclosure within the first 6-months of employment.

**National Institutes of Health, Bethesda, MD, USA** March 2004 – 2007  
**Postdoctoral Fellow, Cartilage Biology and Orthopaedics Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)**

- Studying signaling pathway (e.g., Wnt, Notch and TGF $\beta$  signaling pathways) involvement in musculoskeletal tissue damage/repair for orthopaedics and cartilage tissue engineering strategies.
- Experience with mammalian cell culture, aseptic techniques, RNA isolation, cDNA synthesis, PCR (conventional/real-time), site-directed mutagenesis, transfection/transduction approaches, gene silencing techniques (RNAi/shRNA) and microarrays.
- Hands-on experience with stem cells and their use as platforms for drug discovery.
- Wrote SOPs and trained personnel in lab on a pathway-specific microarray assay system for human mammalian cells.
- Set-up and trained technical staff, students and postdoctoral fellows on the Flexercell® Tension Plus™ System for mechanical testing. Responsible for its maintenance and trouble shooting.
- Supervised 3<sup>rd</sup> Year Orthopaedic Resident Fellows. Design and directed research projects and trained fellows in bench-top science techniques.
- Optimized an electroporation-based transfection protocol for introducing transgenes into primary human MSCs.
- Established cross-disciplinary collaborations within NIAMS and other academic institutions (Georgetown University and Blood and Marrow Transplant and Cancer Center, University of Minnesota Medical School), which has led to joint research initiatives in the areas of gene therapy and cancer.

**Tissue Regeneration Therapeutics (TRT), Toronto, Canada** Sept. 2003 – March 2003  
**Scientific Advisor/Consultant**

- Provided R&D consulting.
- Wrote and optimized SOPs for bioreactor-based cell expansion technology.
- Trained technical staff on bioreactor cell expansion technology.
- Evaluated candidate technologies for acquisition by TRT.
- Participated in writing industry sponsored grant applications and patent application submissions.

**BoneTec Corp., Toronto, Canada** Sept. 2001 – Dec. 2003  
**R&D Consultant**

- Provided R&D consulting for BoneTec Corp.'s Stem Cell/Biomaterial technology platform.
- Co-authored the first business plan for BoneTec Corp, including detailed market analysis and financial projections.

**University of Toronto, Canada** Sept. 1999 – Feb. 2004  
**Ph.D. Graduate Research Associate**

- Developed a novel cell culture system for isolating and expanding mammalian cells for cell-based and tissue engineering strategies using stirred suspension bioreactors.
- Optimized inoculation density, feeding schedule, O<sub>2</sub> tension to maximize bioreactor performance.
- Designed and implemented statistical factorial design experiments and analysis to develop a serum-free bioreactor culture system for the cultivation of mammalian cells.
- Optimized cell culture process for scale-up (10 ml to 100 ml).
- Experienced with flow cytometry, FACS, magnetic-cell sorting.
- Work formed the basis of intellectual property and participated in preparing patent application submissions.

**University of Toronto, Canada** Sept. 1997 – Sept. 1999  
**Master of Applied Sciences (M.A.Sc.) Graduate Research Associate**

- Developed a three-dimensional, dynamic culture system for culturing mammalian cells on calcium phosphate and polymeric-based biomaterials for tissue engineering applications.
- Experienced in scanning electron microscopy and back-scattered electron microscopy, biodegradation assays, surgical procedures (diffusion chambers and trans-femoral defects) using small animal models.

**Millenium Biologix Inc., Kingston, Canada** May – Sept. 1997  
**Natural Sciences and Engineering Research Council (NSERC) Industry Sponsored Internship**

- Conducted research on bone replacement biomaterials for orthopaedic applications, including biodegradation assays, cell differentiation assays and mechanical testing.
- Performed in vitro and in vivo (small animal models) experiments with biomaterials.

**University of Toronto, Canada** Summer 1996  
**Research Assistant, Department of Chemical Engineering**

- Worked on the optimization of a biomaterial for wound healing applications.
- Developed an assay for quantifying the concentration of a carbohydrate polymer (hyaluronan) in cell-free porcine skin samples.
- Awarded J. Edgar McAllister Undergraduate Fellowship to pursue this summer research work.

**Ontario Hydro Technologies, Etobicoke, Canada****May – Sept. 1995****Junior Engineer In-Training**

- Optimized a tritium decontamination facility and assessed its environmental impact through experimental work performed on a bench-scale version of the facility.
- Contributions to work were published and presented at the 16<sup>th</sup> Annual Symposium on Fusion Engineering (1995).

**INTELLECTUAL PROPERTY**

Ennis J, Gomez J, **Baksh D** and Davies JE. Immune Privileged and Modulatory Progenitor Cells. PCT patent application filed May 5<sup>th</sup>, 2006.

**Baksh D**, Zandstra PW, and Davies, JE. Serum-Free Suspension Culture System For Mesenchymal Progenitor Cells. PCT patent application filed March 5<sup>th</sup>, 2004 (Serial #: PCT/CA06/549/910).

Sarugasur R, **Baksh D**, Hosseini. M and Davies JE. A Method of Isolating of, Expansion, and Differentiation of Connective Tissue Precursor Cells from the Cells of Wharton's Jelly of Human Umbilical Cord. US Provisional patent application filed February 11<sup>th</sup>, 2003.

**Baksh D**, Zandstra PW, and Davies JE. Progenitor Cell Populations, Expansion Thereof and Growth of Non-hematopoietic Cell Types and Tissues Therefrom. PCT patent application filed April 23<sup>rd</sup>, 2002 (Serial #: PCT/CA02/00550).

**AWARDS AND SCHOLARSHIPS**

June 2005	Junior Investigator Travel Award, International Society for Stem Cell Research
June 2005	Outstanding Oral Presentation, NIAMS Annual Scientific Retreat
September 2002	University of Toronto Fellowship, Department of Chemical Engineering
2002	The Norman F. Moody Award for Academic Excellence in Doctoral Research
May 2002	Recipient of an Ontario Graduate Scholarship (2 years) for doctoral studies
September 2001	The Institute of Biomaterials and Biomedical Engineering Fellowship
May 2000-2002	Natural Sciences and Engineering Research Council (NSERC) PGSS (Ph.D. Level) (2 years)
Sept. 1998-1999	University of Toronto Fellowship
Sept. 1997-1998	NSERC-IPS (Industrial Postgraduate Scholarship)
Summer 1996	J. Edgar McAllister Undergraduate Fellowship
1994	St. Michael's College Course Scholarship, U of T
1991	Canada Scholar, Canada Scholarship (4 years)
1991	Entrance Scholarship, U of T

**ACTIVITIES AND AFFILIATIONS (Past & Present)**

- Active member of the International Society of Stem Cell Research (ISSCR) 2004-Current
- Junior Investigator Committee (JIC) – ISSCR, JIC Advisory Board Member, holding position of Policy & Administrator 2005-Current
- Tissue Engineering Society International (TESI), Student Program Co-Chair 2003
- Nominated and accepted position as secretariat for Canadian Biomaterials Society, Toronto Student Chapter 2003-2004
- Member of StemCell Network Canada 2003-2004
- Canadian Biomaterials Society Toronto Student Local Chapter, Executive Member 2002-2003
- American Society for Biomaterials 1997-2002
- Canadian Biomaterials Society 2001-2004
- Golden Key National Honor Society
- Graduate Student Union Representative (1997-1998)

**INVITED JOURNAL REVIEWER**

Biotechnology & Bioengineering  
Journal of Bone and Mineral Research  
Journal of Cellular Biochemistry  
Journal of Cellular Physiology  
Science  
Stem Cells  
Tissue Engineering

**PUBLICATIONS**

### **Selected Peer-Reviewed Journal Articles**

1. Janjanin S, Djouad F, Shanti RM, **Baksh D**, et al. Human palatine tonsil: a new potential tissue source of multipotent mesenchymal progenitor cells. *Arthritis Res Ther* 2008 Jul;10(4):R83.
2. **Baksh D**, Boland, GM, and Tuan RS. Canonical Wnt mediators are capable of functional antagonism in mesenchymal stem cells undergoing differentiation (*Journal of Cellular Biochemistry* 2007 Aug 1:101(5):1109-24).
3. **Baksh D** and Tuan RS. Differential effects of Wnts on bone marrow-derived mesenchymal stem cell developmental potential (*Journal of Cellular Physiology*, In Press 2007).
4. **Baksh D**, Yao R, and Tuan RS. Comparison of Human Umbilical Cord Perivascular Cells and Bone Marrow-Derived Mesenchymal Stem Cells: Proliferative and Multilineage Differentiation Potential (*Stem Cells*, In Press 2007).
5. **Baksh D**, Zandstra PW, and Davies JE. Osteogenic cells derived from a CD49e<sup>low</sup> subpopulation of bone marrow-derived cells can undergo long-term expansion in non-contact suspension culture (*Biotechnology and Bioengineering*, Submitted 2007).
6. **Baksh D**, Davies JE, and Zandstra PW. The Soluble Factor Crosstalk Between Human Bone Marrow-Derived Hematopoietic and Mesenchymal Cells Enhances In Vitro CFU-F and CFU-O Growth and Reveals Heterogeneity In The Mesenchymal Stem Cell Compartment. *Blood*. 2005 Nov 1;106(9):3012-9.
7. Sarugaser R, Lickerish D, **Baksh D**, Hosseini M, and Davies JE. Human umbilical cord perivascular (HUCPV) cells as a source of mesenchymal progenitors. *Stem Cells* 2005 Feb;23(2):220-9.
8. **Baksh D**, Davies JE, and Zandstra PW. Adult human bone marrow derived mesenchymal progenitor cells are capable of adhesion independent survival and expansion. *Experimental Hematology* 2003.
9. **Baksh D**, Davies JE, and Kim S. Three dimensional matrices of calcium polyphosphate support bone growth in vitro and in vivo. *Journal of Material Science: Materials in Medicine* 1998;9:743-748.

### **Invited Reviews**

1. Rousche K\*, **Baksh D\***, and Tuan RS. The Various Pathways of Cytokine Signaling – Wnt Signaling to Further Targeted Therapies in Rheumatology. *Further Targeted Therapies in Rheumatology* (Submitted, 2006). \*Authors contributed equally.
2. Song L, **Baksh D**, and Tuan RS. Mesenchymal Stem Cell-based Cartilage Tissue Engineering: Cells, Scaffolds, and Biology. *Cytotherapy* 2004;6(6):596-601.
3. **Baksh D**, Song L and Tuan RS. Adult Mesenchymal Stem Cells: Characterization, Differentiation, and Application in Cell and Gene Therapy. *J Cell Mol Med*. 2004 Jul-Sep;8(3):301-16.

### **Book Chapters**

1. **Baksh D** and Davies JE. (2007) Culture of Mesenchymal Stem Cells in Adhesion-Independent Culture Conditions. In *Methods in Cell Biology: Stem Cell Culture*. Academic Press.
2. Ennis J, Gomez A, Sarugaser R, **Baksh D** and Davies JE. (2007) Isolation, Characterization and Differentiation of Human Umbilical Cord Perivascular Cells (HUCPVCs). In *Methods in Cell Biology: Stem Cell Culture*. Academic Press.
3. Madlambayan GJ, **Baksh D**, and Zandstra PW. (2003) A Systematic Approach to the Development of Stem Cell Expansion Cultures. In *Handbook of Adult & Fetal Stem Cells* (Eds. R.P. Lanza, H.M. Blau, D.A. Melton, M.A.S. Moore, E.D. Thomas, C.M. Verfaillie, I.L. Weissman and M.D. West). Academic Press, San Diego, USA.
4. Davies JE, Karp JM and **Baksh D**. (2001) Mesenchymal Cell Culture: Bone. In *Methods in Tissue Engineering*, (Eds. Anthony Atala and Robert Lanza). Academic Press, San Diego, USA.
5. **Baksh D** and Davies JE. (2000) Design Strategies for Three Dimensional in vitro Bone Growth in Tissue Engineering Scaffolds. In *Bone Engineering*, (Ed. JE Davies). EM squared Inc., Toronto, Canada.
6. Davies JE and **Baksh D**. (2000) Bone Tissue Engineering on Biodegradable Scaffolds. In *Tissue Engineering for Therapeutic Use 4* (Ed. Yoshito, Y). Elsevier Science BV, New York, USA.

### **CONFERENCE PROCEEDINGS AND TRANSACTIONS**

1. Baksh D, Zagame Z, Nixon A, Doshi K, and Ronford V. Optimization of epidermal development in bilayered living cellular construct (BLCC) by human dermal fibroblasts. 2010 Annual Hilton Head Workshop, Regenerative Medicine: Advancing Next Generation Therapies, March 10-14, 2010, Hilton Head Is, SC. Podium Presentation.
2. Baksh, D. and Ronford, V. (2009) The impact of cell ratio on cross-talk between fibroblast and keratinocytes during the production of human bilayered skin substitutes. SAWC/WHS Dallas, TX April 29<sup>th</sup>. Podium Presentation.

3. Baksh, D. (2008) Impact of cell potency on bilayered living skin substitute production. The 9<sup>th</sup> Annual Wound Healing: Science and Industry. St. Thomas, US Virgin Islands December 12-14. Invited Podium Presentation.
4. **Baksh, D.** (2008) The importance of cross-talk between dermal fibroblasts and keratinocytes during the manufacturing process of skin equivalents. The annual CELLutions Summit Meeting, Boston, MA August 11-13. Invited Podium Presentation.
5. Byers BA, Graw BP, **Baksh D**, Mauck RL, Rackwitz L and Tuan RS. (2007) Compromised Maturation of Tissue-Engineered Cartilage in the Presence of Pro-Inflammatory Cytokines IL1 $\beta$  and TNF $\alpha$ . The 53<sup>rd</sup> Annual Meeting of the Orthopaedic Research Society February 11-14, San Diego, CA, USA, Poster Presentation.
6. **Baksh D**, Yao R, and Tuan RS. (2006) Human Umbilical Cord Perivascular Cells as a Mesenchymal Stem Cell Source: Proliferative and Multilineage Differentiation Potential. The 4<sup>th</sup> Annual Meeting of the International Society of Stem Cell Research June 29-July 1, Toronto, Canada. Poster Presentation.
7. **Baksh D**, Taboas JM, and Tuan RS. (2006) Mechanical Stimulation Enhances Canonical Wnt Signaling and Effects Osteogenesis in Human Mesenchymal Stem Cells. The 52<sup>th</sup> Annual Meeting of the Orthopaedic Research Society March 19-22, Chicago, IL, USA. Podium Presentation.
8. **Baksh D**, Yao R, and Tuan RS. (2006) Comparison of Human Umbilical Cord Perivascular Cells and Bone Marrow-Derived Mesenchymal Stem Cells: Proliferative and Multilineage Potential. The 52<sup>th</sup> Annual Meeting of the Orthopaedic Research Society March 19-22, Chicago, IL, USA. Poster Presentation.
9. **Baksh D** and Tuan RS. (2005) Differential Effects of Wnts on Human Bone Marrow-Derived Mesenchymal Stem Cell Development. The 3<sup>rd</sup> Annual Meeting of the International Society for Stem Cell Research June 23-June 25, San Francisco, CA, USA. Poster Presentation.
10. **Baksh D**, Boland GM, and Tuan RS. (2005) Wnt Regulation of Mesenchymal Stem Cell Proliferation and Osteogenesis. The 51<sup>st</sup> Annual Meeting of the Orthopaedic Research Society February 20-23, Washington, DC, USA. Podium Presentation.
11. **Baksh D**, Zandstra PW, and Davies, JE. (2004) Long-term Suspension Culture of Human Bone arrow-Derived Mesenchymal Progentior Cells Provides a Source of Functional Osteogenic Cells. The 50<sup>th</sup> Annual Meeting of the Orthopaedic Research Society March 21-23, San Francisco, CA, USA. Podium Presentation.
12. **Baksh D**, Zandstra PW, and Davies JE. (2003) Adult Human Bone Marrow Derived Mesenchymal Progenitor Cells Capable of Adhesion Independent Survival and Expansion. The 49<sup>th</sup> Annual Meeting of the Orthopaedic Research Society February 2-5, New Orleans, LA, USA. Podium Presentation.
13. **Baksh D**, Zandstra PW and Davies JE. (2003) Adult Human Bone Marrow Derived Mesenchymal Progenitor Cells Capable of Adhesion Independent Survival and Expansion. 5<sup>th</sup> International Meeting of the Tissue Engineering Society International December 8-12, Kobe, Japan. Podium Presentation.
14. **Baksh D**, Zandstra PW and Davies JE. (2002) Expansion of Human Mesenchymal Precursors for Scaffold-based Bone Tissue Engineering Applications. 17<sup>th</sup> Annual European Conference on Biomaterials September 11-14, Barcelona, Spain. Podium Presentation.
15. **Baksh D**, Zandstra PW and Davies JE. (2002) Expansion of Human Mesenchymal Precursor Cell Numbers in Suspension Bioreactors for Scaffold-based Bone Tissue Engineering Applications. American Society for Biomaterials 28<sup>th</sup> Annual Meeting April 24-27, Tampa, FL, USA. Podium Presentation.
16. **Baksh D**, Zandstra PW and Davies JE. (2002) Expansion of Human Osteogenic Progenitors in Stirred Suspension Bioreactors. The 48<sup>th</sup> Annual Meeting of the Orthopedic Research Society February 10-13<sup>th</sup>, Dallas, TX, USA. Podium Presentation.
17. **Baksh D**, Zandstra PW and Davies JE. (2001) Expansion of Human Mesenchymal Precursor in Suspension Bioreactors for Scaffold-based Bone Tissue Engineering Applications. European Tissue Engineering Society 1<sup>st</sup> Biennial Meeting November 7-10, Friburg, Germany. Podium Presentation.
18. **Baksh D**, Zandstra PW and Davies JE. (2001) Expansion of CFU-O Progenitors in Suspension. The 23<sup>d</sup> Annual Meeting of The American Society for Bone and Mineral Research October 12-16, Phoenix, AZ, USA. Poster Presentation.
19. **Baksh D**, Zandstra PW and Davies JE. (2001) Expansion of Bone Marrow-Derived Stromal Progenitor Cell Numbers in a Stirred Suspension Bioreactor. American Society For Biomaterials 27<sup>th</sup> Annual Meeting St.Paul/Minneapolis, April 24-29, Minnesota, USA. Podium Presentation.

## REFERENCES

References available upon request.